



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

93536d

Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

October 22, 2002

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER
Ref. KAN 2003-02

Mr. Kenneth Tomlon
President & Chief Executive Officer
Good Samaritan Health Systems
10 East 31st Street
Kearney, NE 68847

Dear Mr. Tomlon:

During an inspection of your blood bank operation located at the above address on August 29-30, 2002, an investigator from this office documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680 as follows:

Failure to investigate adverse reactions and maintain appropriate records. [21 CFR 606.170(a)] Specifically, of approximately thirty-eight transfusion reactions documented during 2002, only five have been investigated.

The above identified deviation is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

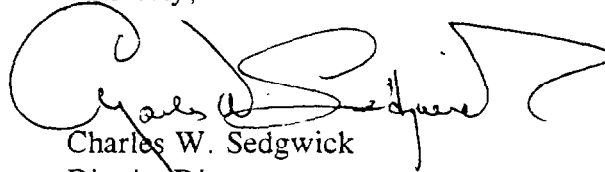
You should take prompt measures to correct this deviation. Failure to promptly correct this deviation may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation and to prevent recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Mr. Kenneth Tomlon
Good Samaritan Health Systems
October 22, 2002
Page 2

Your reply should be sent to Nadine Nanko Johnson, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick". The signature is stylized with a large, looping initial "C" and a long, sweeping horizontal stroke.

Charles W. Sedgwick
District Director
Kansas City District

cc: Dr. Alden F. Kielhorn
Laboratory Medical Director
Good Samaritan Health Systems
10 East 31st Street
Kearney, NE 68847